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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,555	03/01/2002	Jerald K. Rasmussen	54652US008	3817

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
	1651

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	RASMUSSEN ET AL.	
10/087,555		
Examiner	Art Unit	
David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 March 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date, _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

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DETAILED ACTION

The amendment of 3/19/04 amended the abstract and claims 12 and 13, and added new claim 18.

Claims examined on the merits are 12-18 which are all claims in

5 the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 12-18 are rejected under 35 U.S.C. 103(a) as being 10 unpatentable over Rasmussen et al (5,993,935) in view of Rothschild et al (6,057,096) and Berenson et al (5,215,927) for the type of reasons set forth in the previous office action of 12/16/03.

The claims are drawn to an azlactone-functional support containing a covalently bound biologically active substance and whole 15 target cells bound to the substance from a mixture of whole cells, and wherein the support contains a base polymer that has been identified as exhibiting minimal nonspecific binding of non-target whole cells in the mixture.

Rasmussen et al disclose (col 9, lines 15-62) an azlactone-functional support (col 5, lines 20-67) containing a covalently bound ligand for use as an adsorbent to carry out affinity separations (col 9, line 59).

Rothschild et al disclose coupling cell adhesion molecules to a support to carry out separation of target cells from a mixture of 25 cells (col 7, lines 36-61, and col 43, lines 23-57).

Berenson et al disclose using immobilized avidin to isolate target cells that have been reacted with a biotinylated antibody to form a biotinylated cell complex from a mixture of cells (col 3, lines 32-68).

5 It would have been obvious to use as the ligand of Rasmussen et al a ligand that binds cells and use the bound ligand to bind and separate target cells from a mixture of cells as suggested by Rothschild et al and Berenson et al isolating target cells from a mixture of cells using an immobilized ligand that binds the target 10 cells or that binds a complex of the target cells containing a component that binds to the ligand. Rasmussen et al disclose polymer supports that are the same as disclosed in the present specification, and the polymer support of Rasmussen et al will inherently have minimal nonspecific binding for certain non-target cells in a mixture 15 of cells. The claims defining the base polymer support in terms of being identified as having minimal nonspecific binding for non-target cells does not make the base polymer support different than disclosed by Rasmussen et al. Furthermore, it would have been obvious to select from the polymer supports disclosed by Rasmussen et al a polymer 20 support that has minimal nonspecific binding for non-target cells when using the polymer support for separating cells since a polymer support that binds a significant number of non-target cells would have been expected to bind a mixture of target and non-target cells, and not isolate a pure culture of target cells. As to claim 12, binding 25 target cells from blood would have been suggested by Rothschild et al

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disclosing selectively binding leukocytes (col 7, line 41) and Berenson et al disclosing selectively binding target cells in blood (col 22, line 48).

Response to Arguments

5 Applicant's arguments filed 3/19/04 in the preliminary amendment have been fully considered but they are not persuasive.

Applicants urge that the invention is not directed to merely any support for whole cell selection, but involves identification of a support particularly suited for whole cell selection because the 10 support has minimal nonspecific binding of non-target cells in a mixture of cells. Applicants point out that claim 12 has been amended to require the polymer support to be identified as exhibiting minimal nonspecific binding of non-target whole cells of a mixture of whole cells.

15 This argument is unpersuasive since the polymer support of Rasmussen et al can be the same as disclosed in the present specification, and inherently has minimal nonspecific binding for certain non-target cells. Selecting the polymer support of Rasmussen et al by a process of identifying the support as having minimal non-20 specific binding for non-target cells does not make the polymer support different. The minimal nonspecific binding of the claims can be for any non-target cells, and the polymer support of Rasmussen et al will inherently have minimal non-specific binding for some types of non-target cells.

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Applicants urge that the claims require a species within a genus. However, it would have been obvious to use any of the polymer supports disclosed by Rasmussen et al when binding target cells from a mixture of cells as suggested by Rothschild et al and Berenson et al.

- 5 Rasmussen et al intend any of the polymer supports disclosed to be used for affinity separation when containing a bound ligand. The ligand of Rasmussen et al can be Protein A (col 17, line 39) which is a ligand disclosed by Berenson et al (col 21, lines 34-35) for binding target cells, and which is disclosed in the present specification for 0 binding target cells (Example 11). Also the ligand of Rasmussen et al can be an antibody (col 9, lines 36-45) which is a ligand that can be used by Rothschild et al (col 43, lines 32-35) and Berenson et al (col 21, line 36) for binding target cells, and which is disclosed in the present specification for binding target cells (col 5, lines 18-20).
- 5 Rasmussen et al intend the ligand-containing polymer support to be used for affinity separation of any material for which the ligand has specific affinity. When Rothschild et al and Berenson et al are considered, it becomes clear that ligand-containing polymer supports disclosed by Rasmussen et al can be used for affinity separation of 0 target cells. Identifying a polymer support having minimal nonspecific binding for non-target cells as claimed, does not require a ligand-containing polymer support different than disclosed by Rasmussen et al that would have been obvious to use for affinity separation of target cells as suggested by Rothschild et al and 5 Berenson et al.

Double Patenting

Claims 12-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,952 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of the claims of the patent require producing a support containing bound cells as presently claimed.

Response to Arguments

An argument has not been presented in response to this rejection.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

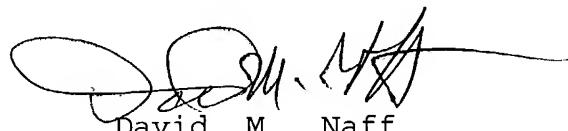
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff

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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-5 0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained 10 from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-15 9197 (toll-free).

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David M. Naff
Primary Examiner
Art Unit 1651

DMN
5/26/04